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PATENTS

IN THE UNITED STATES PATENT AND TRADMARK OFFICE

Applicants: Brioni, *et al.*

Serial No.: 09/985,974

Filed: November 7, 2001

Title: THE USE OF SELECTIVE DOPAMINE RECEPTOR AGONISTS FOR TREATING SEXUAL DYSFUNCTION

Case No.: 6753.US.02

Group Art No.: 1617

Examiner: Bahar, Mojdeh

CERTIFICATE OF MAILING (37 CFR 1.8(a)): I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

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RESPONSE

Dear Sir:

The following is in response to the FINAL ACTION mailed July 16, 2003, having a period of response through October 16, 2003.

REMARKS

The following is in response to the Office Action, which was made final and mailed July 16, 2003, in the above captioned application.

Claims 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 are pending. Claims 1, 5, 15-22 and 26 (all in part), 3, 7, 10, 13, 24, 28, and 30 have been cancelled. Claims 1, 5, 22 and 26 (all in part), 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Glase *et al.*, and Zorn *et al.*, in view of Sanner (USPN 5,714,487). The rejection is respectfully traversed for the following reasons.

To establish a *prima facie* obviousness under § 103(a), the Examiner must identify, from a source other than Applicant's own specification both (i) a suggestion to modify the teachings of the prior art reference to achieve the presently claimed invention, and (ii) a reasonable expectation of success in making and using the modified procedure.

Glase *et al.*, and Zorn *et al.*, teach that N-[[4-(2-cyanophenyl)-1-piperazinyl] methyl benzamide and CP-226,629, respectively, are selective dopamine D4 agonists that can be useful in treating schizophrenia, emotional and cognitive disorders.

Sanner teaches that ligands of the D4 dopamine receptor are useful in the treatment of disorders of the dopamine system in general (Col. 8, lines 24 through 28, and Col. 8, lines 34 through 41). Sanner does not teach that the compounds are either agonists or antagonists – it is known in the art that the term ligand includes agonists as well as antagonists and partial agonists. Accordingly, the compounds disclosed by Sanner may induce either vasoconstriction or vasodilation, and a multitude of other effects mediated through the D4 receptor depending on their pharmacological role. This concept is further stressed in Sanner in Col. 21, lines 48 through 57, specifically "They [The novel compounds] are therefore able to function as therapeutic agents in the treatment of a variety of conditions in mammals, the treatment or prevention of which can be effected or facilitated by an increase or decrease in dopamine mediated neurotransmission".

Claims 1, 5, 22, 26, 2, 4, 6, 8, 9, 11, 12, 14, 23, 25, 27, and 29 of the present application are directed to a method of treating male sexual dysfunction – most specifically erectile dysfunction - by administering therapeutically effective amounts of dopamine D4 receptor agonists.

Applicants submit that in view of the above there is no suggestion or incentive, or even a reasonable expectation of success in Sanner, Glase and Zorn, alone or in combination, for one skilled in the art to produce a method of treating sexual dysfunction in a mammal by administering a D4 dopamine agonist.

Accordingly, Applicants respectfully submit that the pending claims are patentable over the cited prior art and urge allowance of the claims.

Respectfully submitted,
Brioni, *et al.*

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